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REMOTE MEDICAL DIAGNOSIS SYSTEM (RMDS) ADVANCED DEVELOPMENT MODEL (ADM) TEST PLAN FOR EVALUATION OF IMAGE FIDELITY REQUIREMENTS FOR RADIOGRAPH TRANSMISSION

11115

WT/Rasmussen, I Stevens, PD, Hayes (MOSC) KM Newman (WESTEC Services, Inc)

//| July 1981 /

Prepared for Naval Medical Research and Development Command

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ADMINISTRATIVE INFORMATION

This Technical Document is one in a series of reports for the Remote Medical Diagnosis System (RMDS), Program Element 64771N, Project M0933-PN (NOSC 512-CM38), sponsored by the Naval Medical Research and Development Command, Code 45. It contains the test plan for an experimental evaluation of image fidelity requirements for radiograph transmissions over the RMDS Advanced Development Model (ADM) terminals. This document was prepared by the NOSC Bioengineering Branch (Code 5123) and WESTEC Services, Inc (Contract N66001-78-M-0669) between March and May 1978. The evaluation testing described in this test plan was conducted subsequently, during the period October 1978 to April 1979. The results of that testing are documented in NOSC Technical Report 683.

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of radiographs over the Remote Medical Diagnos	sis System (RMDS) advanc	ed development model terminals.			
The objectives of this evaluation were (1) to det	ermine which, if any, of th	e various operational modes of the			
RMDS ADM terminal would satisfy the image fi	delity requirements for cli-	nical diagnosis of video-transmitted			
radiographs and (2) to establish quantitative and	qualitative values or relati	ionships delineating the image			
fidelity requirements necessary for professional	radiologists to make correc	et and confident diagnoses from			
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SECTION 1

INTRODUCTION

1.1 PURPOSE

This document provides the test plan and guidelines for the experimental evaluation of video transmissions of radiographs over the Remote Medical Diagnosis System (RMDS) Advanced Development Model (ADM) terminals. The purpose of this evaluation was to determine which, if any, of the various operational modes of the RMDS ADM terminal would satisfy the image fidelity requirements for clinical diagnosis of video-transmitted radiographs. The objective of this evaluation was to establish quantitative and qualitative values or relationships delineating the image fidelity requirements necessary for professional radiologists to make correct and confident diagnosis of video-transmitted radiographs.

1.2 BACKGROUND

The mission of the RMDS is to improve medical diagnosis at remote sites. This is accomplished by transmitting medical data and diagnostic information between remote ship or shore sites and full-capability medical centers. The RMDS will enable the medical personnel at a remote site to contact a physician at a diagnostic center (ashore or shipboard) and transmit a visual and auditory presentation of the medical data needed for diagnosis, such as patient history, laboratory tests, ECG tracings, x-ray images, images of a patient injury, heart-lung sounds, and verbal descriptions. By return link, the physician will be able to send diagnosis and treatment information. The communication requirements are satisfied by any two-way, voice-grade, narrowband communication channel such as telephone line, hf or uhf radio, or satellite link.

The system as a whole consists essentially of the RMDS terminals, the existing voice-grade communication links used to interconnect the terminals, and user personnel. Contained in the terminals is all the hardware that is unique to the system: TV camera, TV monitor, x-ray light box, electronic stethoscope, ECG monitor, audio tape recorder, audio handsets, and the electronics package, consisting of signal modulator, demodulator, and modems.

Shipboard feasibility tests of an early RMDS were completed during FY 75/76. This testing showed that the concept was feasible and that equipment could be developed to meet the requirements by using available technology (ref 1). Because of various constraints (eg, narrow bandwidth, short transmission times, etc.), the resolution and gray scale to be achieved in transmitting and displaying radiographic data should be

^{1.} NOSC TR 659, Feasibility Tests of the Remote Medical Diagnosis System, WT Rasmussen and I Stevens (NOSC) and JA Kuhlman (WESTEC Services, Inc.), January 1981.

kept to a minimum to meet essential requirements. The gray scale requirements for display have been satisfactorily established in existing literature to be at least 6 bits per picture element, with 8 bits preferred. In order to derive minimum resolution data, eight radiologists were tested and the results analyzed in FY 77, using a special digital closed-circuit television system to simulate the RMDS equipment (ref 2).

As a result of those feasibility and radiology tests, NOSC undertook a development project to produce two Advanced Development Model RMDS terminals; the ADMs were procured in September 1977. The RMDS ADM terminals were tested for technical performance at NOSC from September 1977 to September 1979. During this period, the ADMs were tested at sea, with one terminal aboard the USS ENTERPRISE (CVN-65) from 28 February to 5 March 1978. The image fidelity evaluation testing of radiograph transmission via the ADMs, per this test plan, was performed during the period October 1978 to April 1979. The at-sea, laboratory, and radiology test results are documented in separate NOSC Technical Reports.

1.3 EXPERIMENTAL CONSTRAINTS AND CONSIDERATIONS

- a) The tests had to be structured for minimum impact on the radiologists' professional duties, without detrimental impact on good experimental design and procedural practices.
- b) The tests had to provide sufficient data for statistically valid analyses to support the conclusions reached.
- c) The tests had to conform to the available and existing equipments.
- d) The validated test results obtained from this effort were utilized as some of the principal inputs in developing an RMDS procurement specification.

1.4 PARAMETRIC CONSIDERATIONS

The successful (ie, accurate and confident) diagnosis of a radiographic image by a professional radiologist depends almost exclusively on the fidelity of the image viewed. The fidelity of radiographs transmitted electronically from one location to another is influenced considerably by various parameters such as transmission mode, equipment characteristics, etc. Under test were the parameters that affect image fidelity, as follows:

- a) Gray level quantization, which can make natural gray level changes appear as artificial edge structures, or which can mask subtle gray level changes (ie, analog vs. digital transmission mode).
- 2. NOSC TR 150, Resolution Requirements for Slow-Scan Television Transmission of X-rays, FH Gerber, 19 September 1977.

- b) Additive noise in the transmission signal, which gives a random, textured pattern to the image, thereby possibly masking natural texture or detail (ie, high vs. low signal-to-noise ratio).
- c) Spatial resolution of the image presented, which affects the level of detail that can be detected under low noise conditions (ie, fine vs. coarse resolution).

The tests performed were directed toward resolving both the nature and the impact of these three parameters on radiologists' diagnostic performance in evaluating transmitted radiographs. In addition to the three principal parameters, the fidelity of the transmitted images may be affected by the settings of the contrast and brightness controls at the TV monitor. Therefore, any changes in these settings made by the radiologists were monitored and recorded during the tests.

SECTION 2

APPROACH AND DESIGN

2.1 EXPERIMENTAL APPROACH AND PARAMETERS

The experimental approach taken involved the use of two groups of test subjects (radiologists): an RMDS Radiology Test Group and a Control Radiology Test Group. The test data from each group were analyzed and compared individually as well as by groups. In the following two subsections, the experimental variables considered for each group are listed.

2.1.1 RMDS Radiology Tests Experimental Variables

Each of the three variables below has two levels:

- a) Transmission Mode:
 - Digital (64 shades of gray) Transmission
 - Analog Transmission
- b) Signal-to-Noise Ratio (SNR):
 - High SNR
 - Low SNR
- c) Resolution:
 - Fine (256 x 512 raster) Resolution
 - Coarse (256 x 256 raster) Resolution

Combining the variables and levels in a true factorial design* would result in 2³ experimental conditions. However, since there is no progressive degradation of SNR in digital transmission, the theoretical combinations of digital transmission and low SNR (digital x low SNR x fine resolution; digital x low SNR x coarse resolution) are not valid. Therefore, the RMDS Radiology Tests consisted of the six experimental conditions shown in table 1.

^{*}In a factorial design the effects and interactions of two or more experimental variables are observed simultaneously.

TRANSMISSION MODE	ABBREVIATION	LABEL
Digital; High SNR; Fine Resolution	DHF	I
Digital; High SNR; Coarse Resolution	DHC	II
Analog; High SNR; Fine Resolution	AHF	III
Analog; High SNR; Coarse Resolution	AHC	IV
Analog; Low SNR; Fine Resolution	ALF	V
Analog; Low SNR; Coarse Resolution	ALC	VI

Table 1. Six RMDS radiology experimental test conditions.

2.1.2 Control Radiology Tests Experimental Variables

These tests were considered a necessary adjunct to the RMDS Radiology Tests, and compared the differences in findings confidence levels, diagnostic confidence levels, and accuracy of radiographs presented in the following two manners: as a "pure" analog signal (not possible with the RMDS*) via closed circuit television (CCTV); and in the "direct" manner, with a light box. Resolution of the CCTV image was made equivalent to that of the fine resolution mode of the RMDS Tests by band-limiting the video signal. The SNR was also fixed for the above two variables. Thus, the Control Tests were performed under two experimental conditions:

- Direct I
- CCTV II

2.2 HYPOTHESES

Two principal hypotheses were tested by statistical analyses of the data:

a) With the combinations of fine resolution and high SNR, for both analog and digital transmission modes, diagnoses can be made which are, statistically, not significantly different in terms of confidence level and accuracy from those made using CCTV images of equivalent spatial resolution. In other words, the quantization level of 6 bits per picture element, as used in the RMDS for digital transmission, and the frozen noise of the received images for both digital and analog transmission modes degrade neither the confidence level nor the accuracy of radiographic diagnoses.

^{*}Since the RMDS utilizes a memory, those radiographs transmitted in the analog mode are digitized to a certain degree.

b) Fine resolution, in both the digital and analog RMDS in the statistically more confident and accurate diagnoses than the lution and significantly reduces diagnostic inaccuracies.

In addition, other quantitative results, as outlined in paragraph 3.3 below. were gated during the tests.

2.3 TEST REQUIREMENTS

2.3.1 RMDS Radiology Test Requirements

a) Radiographs

Thirty-six radiographs were used, divided into six sets radiographs each. These 36 radiographs were selected from over sixty case from Naval Regional Medical Center, San Diego. The six radiographs of each set consists six different disorders, with all sets balanced as equivalently as possible with resorbathology, contrast, density, and the difficulty of visual and diagnostic interpreted This was done by assigning a Difficulty Ranking Factor (DRF) of 1 (low) to 6 that each radiograph prior to its inclusion in the testing. The DRF was derived to individuals, independently, by consensus.

The six sets (labeled A, B, C, D, E, and F) were then arranger that each set had a radiograph with a DRF of 1 through 6, and each was balance much as possible with respect to pathologies and type (or zone), ie, appended abdomen, chest, or skull. The sequential order of presentation of the radiographs with each set was randomized with respect to the DRF and type. This order was the second for all subjects throughout the testing. Table 2 shows the radiographs used, their order of presentation within the set, the type of radiograph, the assigned DRF, and a primar diagnosis.

b) Subjects

Six experienced radiologists were required. It was estimated that a to two hours would be needed by each radiologist to evaluate and diagnose one set of so radiographs, including time required to record findings and comments. Based on the assumption, at most twelve hours would be required by each radiologist to complete the experiment.

· 2.3.2 Control Radiology Test Requirements

a) Radiographs

All six radiograph sets (A, B, C, D, E, and F) used in the RMDS Radiology Tests were employed. The six radiographs in each set were sequentially ordered as shown in table 2. All six sets were presented in a direct manner with a light box; three of the sets were first presented via closed circuit television (CCTV), making a total of nine sets of evaluations.

<u>Set /#</u>	DRF*	Type (Zone)	Diagnosis
A-1	5	Appendage	Soft tissue hemangioma
2	6	Skull	Fractured mandible
3	3	Chest	(R) LL pneumonia
4	2	Skull	Double floor of sella
5	4	Skuц Abdomen	
6			Prostatic calculi
ס	1	Abdomen	Bilateral adrenal
			calcification
B-1	1	Skull	Broken nose
2	3	Appendage	Osteoid osteoma
3	6	Chest	ASD with 4:1 shunt
4	2	Chest	Alveolar cell calcification
5	4	Skull	Intracranial air & fracture
6	5	Appendage	Fx neck of femur on (R)
-	-	vell and a	2 10 110 11 07 10 110 07 122,
C-1	4	Chest	Calcified mitral annulus
2	2	Chest	Coeci
3	5	Skull	Parietal skull fracture
4	1	Abdomen	Abdominal aortic aneurysm
5	3	Appendage	Avascular necrosis of lunate
6	6	Skull	Nasal spine Fx
	-	, , , , , , , , , , , , , , , , , , ,	riddal opino 1
D-1	4	Chest	Pancoast tumor
2	5	Skull	Multiple myeloma
3	2	Abdomen	Air under (R) diaphragm
4	6	Appendage	Chondrocalcinosis
5	1	Appendage	Fibrous cortical defect
6	3	Chest	Pericardial calcification
			L 32 13 14 14 2 14 14 14 14 14 14 14 14 14 14 14 14 14
E-1	3	Skull	Calvarial hemangioma
2	6	Abdomen	Splenomegaly
3	4	Appendage	Tibial stress Fx
4	1	Abdomen	Osteitis condensans ilii
5	2	Skull	Mucocoele (L) fronal sinus
6	5	Chest	Histiocytosis-x
F-1	3	Abdomen	Abdom coloification (post
L-1	3	Abdomen	Abdom. calcification (post
•	•	C 1	traumatic splenic cyst)
2	2	Chest	Infectious spondylitis TB
3	4	Appendage	Cocci osteomyelitis
4	5	Chest	Calcified myocardial infarct
5	6	Chest	Pneumothorax on (R)
6	1	Skull	Enlarged sella

*DRF = Difficulty Ranking Factor: 1 (Low), 2 (Low/Med Low), 3 (Med Low), 4 (Med High), 5 (Med High/High), 6 (High)

Table 2. Six sets of test radiographs.

b) Subjects

Six radiologists, different from those participating in the RMDS Radiology Tests but of comparable experience, were required. It was estimated that up to one-half hour would be needed by each radiologist to diagnose one set of six radiographs, so that four and one-half hours would be required by each radiologist to evaluate the nine sets.

2.4 EXPERIMENTAL DESIGN

2.4.1 RMDS Radiology Tests

The six experimental conditions (paragraph 2.1.1, table 1), radiographs, and subjects were combined into a modified factorial treatments-by-subjects* design, optimized for isolating the effects of the variables to be tested. Table 3 shows this design. Its pertinent features are:

- a) It was balanced for subjects, conditions and radiograph sets, so that each subject was tested once under each condition with a different set of radiographs.
- b) No set of radiographs was paired with any one experimental condition more than once.
- c) The sequence of conditions/sets presentations was different for each of the six subjects, with respect to both experimental conditions and radiograph sets.

This type of design minimized any possible undesirable interactions between radiographs, subjects, and sequence of experimental conditions presentation.

2.4.2 Control Radiology Tests

In the Control Tests, all six sets of radiographs were used. Each subject was tested under experimental conditions I and II with the appropriate radiograph sets and in the order shown in table 4.

^{*}In a treatments-by-subjects design, all experimental conditions are successively administered to the same subjects.

	<u> </u>						
	SET BOOKLET /	F 1-6	2-6	3-6	4-6	2-6	9-9
9	SET		٥	ں	3	w	a
	EXPTL. COND.	VI (ALC)	1 (DHF) D	V(ALF) C	11 (DHC)	111(AHF)	IV(AHC) D
	SET BOOKLET / COND.	1-5	2-5	3-5	4-5	5-5	9-9
2	SET	۵	∢	O	&	L	A
	EXPTL. COND.	V(ALF) D 1-5	11(DHC) A	111(AHF) D	IV(AHC)	I(DHF)	VI(ALC) A
	BOOKLET / COND.	1-4	2-4	3-4	4-4	5-4	6-4
4	SET	ш	80	8	0	∢	ပ
	BOOKLET / COND.	IV(AHC)	111(AHF)	I (DHF)	VI (ALC) D	V(ALF) A	11(DHC) C 6-4
	ET /		_				
	BOOK	1-3	2-3	3-3	4-3	5-3	6-3
3	SET	J	ıL	ш	L	۵	E
	EXPTL. COND.	III(AHF)	IV(AHC)	VI (ALC) E	V(ALF) F	0 (DHC) 0	1 (DHF) E
	BOOKLET / COND.	1-2	2-2	3-2	4-2	2-5	6-2
2	SET	8	ш	٧	ວ	6 0	Ł
	EXPTL.	(ЭНО)11	V(ALF)	IV(AHC)	I (DHF)	VI (ALC)	111(AHF)
	SET BOOKLET / COND.	1-1	2-1	3-1	4-1	5-1	1-9
-	SET	∢	C	14.	d	C	B
	EXPTL. COND.	I (DHF)	VI (ALC)	11(DHC)	111(AHF)	IV(AHC)	V(ALF)
	SUBJECT COND.	-	2	E	4	5	9

EXPERIMENTAL CONDITIONS:

I = DHF = Digital, High SNR, Fine Resolution II = DHC = Digital, High SNR, Coarse Resolution III = AHF = Analog, High SNR, Fine Resolution IV = AHC = Analog, High SNR, Coarse Resolution V = ALF = Analog, Low SNR, Fine Resolution VI = ALC = Analog, Low SNR, Coarse Resolution

Table 3. RMDS Test check form.

TESTING SEQUENCE

	BOOKLET	7-6 7-63	8-6	9-6	10-6 10-6a	11-6	12-6
		j.	Ę	q	Ü	A	8
	EXPTL. COND. SET	= -	-	1		1	-
	BOOKLET	7-5	8-5	9-5 9-5a	10-5	11-5 11-5a	12-5 12-5a
5	SET	E	Ĵ	8	A	F	0
	EXPTL. COND.	= -	1	= -	ı	11	
			II.				
	BOOKLET	7-4	8-4 8-4 ₃	9-4	10-4 10-4a	11-4	12-4
4	SET	0	¥	Ŧ	Ε	8	U
	EXPTL. COND.	-	=-	-	11	11	-
_	BOOKLET	7-3 7-3a	8-3	9-3	10-3	11-3	12-3 12-3a
.,	138	ပ	ıL	LLI	8	Q	A
	EXPTL. COND. SET	= -	-	=-	-	_	=
	<u> </u>						
2	BOOKLET	7-2	8-2 8-2a	9-2 9-2a	10-2	11-2	12-2
	SET	80	a	4	LL.	U	ы
	EXPTL. COND.		=-	=-	-	=-	-
	SET BOOKLET	7-1	8-1 8-1a	9-1	10-1 10-1a	11-1	12-1 12-1a
-	SET B	4	80	U	0	ш	L.
	EXPTL. COND.	_	= -	-	=-	-	=-
	SUBJECT	7	or .	6	٤	=	12

EXPERIMENTAL CONDITIONS:

I = DIRECT [LIGHTBOX] II = CCTV

Table 4. Control Test check form.

SECTION 3

METHOD AND PROCEDURE

3.1 GENERAL

Both RMDS Radiology and Control Tests were carried out in the Bioengineering facilities, Code 5123, Naval Ocean Systems Center (NOSC). Two RMDS terminals located in the area were used back-to-back, with one system serving as the remote terminal (transmitter) and the other one as the diagnostic center terminal (receiver). Voice communication is one feature of the RMDS, and it was available and used in testing. The remote terminal provided zoom and selective intensity capabilities. In the Control Tests, the RMDS was bypassed and the radiographic image as seen by the TV camera was displayed directly on the subject's TV monitor via a bandpass filter. Figure 1 is a block diagram of the RMDS equipment experimental configuration. A cassette-type tape deck was used for recording any comments made by the subjects throughout the duration of each test session.

In order to insure that each radiograph was repeatedly displayed on the receive TV monitor to each radiologist at the same brightness and contrast, some of the levels, namely the camera lens aperture opening (K), the video level (VL), and the black level (BL) on the ship transmit RMDS terminal, were recorded in advance in terms of the amount of deflection measured on a strip-chart recorder. The settings were determined in such a way that the image displayed on the receive TV monitor was as close as possible to the actual radiograph image; table 5 shows these settings. Thus, throughout the tests the settings in table 5 were used and recorded. Furthermore, the contrast and brightness levels of the receive TV monitor were also monitored and recorded. The monitoring of the last two variables gave an indication as to what the radiologist did to the contrast and brightness on the receive monitor in order to make a diagnosis. Prior to each testing session, all equipments were thoroughly checked for satisfactory performance of all necessary functions, and adjusted, if required, to baseline operating parameters.

Prior to testing, each of the radiologists participating in the experiment was briefed* on the purpose of the RMDS; the reasons for and objectives of the test; the capabilities, features and limitations of the hardware relevant to the experiment (such as the zoom and selective intensity capabilities, etc.); the test facility and procedures; and the test materials such as the test data sheets used for both Test and Control Groups (shown as figure 2). The participants were told that their diagnostic comments would be tape recorded, and they were given an opportunity to familiarize themselves with the equipment, the facilities, and the task to be performed, using three non-test radiographs. The radiologists did not know to which group they belonged.

^{*}See Appendix A for full text of radiologists' briefing.

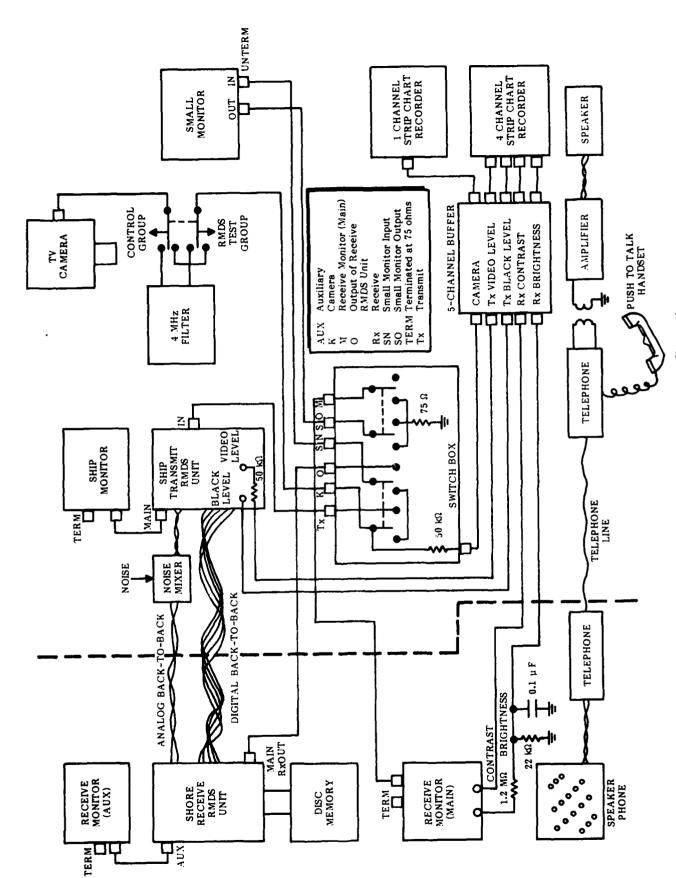


Figure 1. RMDS radiology test equipment configuration.

	MFE K (mm)		001117
Ì	(Camera Lens	GOULD-4	GOULD-3
	Aperture	VL (mm)	BL (mm)
Set /#	Setting)	(Video Level)	(Black Level)
A-1	27	24.5	22.5
2	16	20	18
3	28	24	20
2 3 4 5 6	26	23.5	12
5	28	23.5	15
6	28	23.5	15
B-1	27	25	16
2	27	26.5	16
3 4 5 6	28	26.5	16
4	28	24	20
5	20	24	12
6	28	23.5	16
C-1	28	21	25
	28	24	19
3	27	23	14
4	28	21.5	17.5
5	18	20	17
2 3 4 5 6	27.5	21	20
D-1	27	20	26
2	27	21	18
3	28	2 <u>1</u>	22
4	27	23	14
5	27	23	14
3 4 5 6	28	23	14
E-1	27	18	20
2	28	19	22
3	27	19.5	22
3 4 5	27.5	17	22
5	26	15	25
6	28	20	25
F-1	28	20	26.5
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3	27.5	16	27
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2 3 4 5	26 27	20 20	23 21
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Table 5. Strip chart recorder settings.

HISTORY:

(Include location, extent and visual qualities of radiographic anomalies prompting the findings and diagnoses) FINDINGS/DIAGNOSES:

	CONFIDENCE			
]=Low; 2=Fairly Low; 3=Medium; 4=Fairly High; 5=High	DIAGNOSES			
Low; 3=Medium	CONFIDENCE LEVEL			
CONFIDENCE LEVELS: 1=Low; 2=Fairly	FINDINGS			
		_	2	က

REMARKS (Concerning the above findings/diagnoses):

Figure 2. Test data sheet for Test and Control Groups.

In order to minimize any possible bias on the part of the subjects, the specific experimental condition under test at any one time was not revealed. The fact that different video transmission modes for radiographic transmissions were being investigated was included in the introductory briefing. During this briefing, it was emphasized that the objectives of the experiment were not to evaluate individual professional performance and capabilities, but only to determine and assess the physical parameters necessary for the effective reading and evaluation of transmitted radiographs. The participating radiologists were instructed to read each radiograph as rapidly as possible consistent with professional responsibilities, and to exclude time as a parameter under investigation. The subjects were instructed to record on their test data sheets a numerical value for their level of confidence in the findings and diagnoses arrived at for each radiograph viewed. These values could range from 1 for a low confidence level to 5 for a high confidence level. The subjects were also encouraged to record their comments in the space provided on the data sheet. Depending on whether the subject was part of the Test or Control Group, the corresponding RMDS test sequence was followed.* The radiologists were given a break after completion of each set.

No radiologist was allowed to consult with others during the course of testing. The radiologists were also requested not to discuss observations, impressions, or diagnoses with the other radiologists participating in the study until completion of the entire experiment. After completion of all tests the radiologists filled out a question-naire,** in which each could express likes, dislikes, and suggested areas of improvement.

Radiologists' findings and diagnoses obtained by direct, light box viewing of each radiograph were reviewed by Dr. FH Gerber, Head of Department of Radiology, Naval Regional Medical Center, San Diego, California. Findings and diagnoses which were agreed upon by a consensus of the Control Group were used as a standard against which the findings and diagnoses of the RMDS Radiology Test Group were compared. Thus, the standard for each radiograph was entered on the proper forms (figures 3 and 4). Dr. Gerber compared each radiologist's findings and diagnoses to the standard, and established an Overall Clinical Reading (OCR) evaluation of acceptable, marginal, or unacceptable for each radiograph in each mode.

3.2 DATA ANALYSIS

3.2.1 Quantitative Analysis

The data base for the mathematical treatment of the test results consisted of the numerical confidence level scores, the Overall Clinical Reading evaluations, and the Difficulty Ranking Factors. The first are subjective scores, arrived at by the subjects themselves, while the Overall Clinical Reading scores are an objective measure of performance. The Difficulty Ranking Factors assess the difficulty of visual and diagnostic interpretation.

^{*}See Appendix B for details of the RMDS test sequences.

^{**}See Appendix C for copy of questionnaires.

TEST I II III	DR#	Z STACKDATC	ZN STO	FCL	DCL	FCL	DCI	FC.	DCL	FCL	DCL	FCL	DCL .	PCL	DCL	OVERALL CLIMICAL DEADLES	OMITANT TRANSPORT	CONFIDENCE LEVELS
																	ABBREVIATIONS	= NUMBER = CLASSIFICATION L = FINDING CONF. LEVEL L = DIAGNOSIS CONF. LEVEL = ZOOM USED = NO ZOOM USED

Figure 3. Radiology data collection sheet for RMDS Test Group.

Tas		•				Ì								ſ
9 2		•	DR#	7		8	6		01		# 1		21	
₽0M			CONTROL	II	H	Ħ	н	H	н	Ħ	н	11	1	11
			2											
FINDINGS	DIAGNOSIS	CIB	NZ											
			FCL											
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			FCL											
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			DCL											
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			DCL											
	OVERALL CLINICAL BEADING	AT. BEADT!		_	_									
ABBREVIATIONS			2		_									
RG = RADIOGRAPH								ſ	L					
CLS = CLASSIFICATION	CONFIDENCE LEVELS	CIS -	- CLASSIFICATION	TION	8	OVERALL READING	ADING	Т	_	COM	CONTROL MODES	ODES		
	6.50 6.50 6.50 6.50 6.50 6.50 6.50 6.50	₽ 02 E+	PRIMARYSECONDARYTERTIARY		355	= ACCEPTABLE = MARGINAL = UNACCEPTABLE	BLE L Tarle		13	LIGHT BOX	+	LIVE TV	-5	
NZ = NO 200M USED	. • 91]						

Figure 4. Radiology data collection sheet for Control Group.

The experimental design (modified factorial and conditions by subjects) as well as the performance criteria (confidence levels, percentage errors, and difficulty ranking) allowed application of mathematical analysis. The statistical analyses performed on the interval-scale, confidence level data included: one-way analysis of variance (ANOVA), Duncan's multiple range test, Pearson's correlation, and Wilcoxon's matched-pairs signed-ranks test. The tests used to analyze the ordinal-scale, OCR data included: Wilcoxon's matched-pairs signed-ranks test and Chi-square. The DRF measurements fall between the ordinal and interval scales of data; DRF data were utilized for correlation purposes, via Pearson's correlation, and as subheadings for data groupings. By applying the proper statistical treatments to the raw data, the following issues were investigated:

- a) RMDS Radiology Test Group
 - 1) Evaluate Overall Clinical Reading results by mode.
 - Significant differences.
 - Intrasample variance.
 - 2) Evaluate Overall Clinical Reading results by radiologist.
 - Significant differences.
 - Intrasample variance.
 - 3) Test differences between transmission modes with respect to confidence levels.
 - 4) Determine correlation between confidence levels and Overall Clinical Reading for each transmission mode.
 - 5) Evaluate the relationships between the types of pathology, confidence levels, and transmission modes.
 - 6) Evaluate the effects of the use of the zoom on the Overall Clinical Readings.
- b) Control Radiology Test Group
 - 1) Test difference between results of light box and TV monitor viewing.
 - 2) Based on the Difficulty Ranking Factor (DRF) of the radiographs, repeat the above test.
 - 3) Test the intrasample variance between radiologists.

3.2.2 Qualitative Analysis

The qualitative data, represented by photographic representations of the received radiographic images, by graphs of the collected data, by the brief written comments on the individual test data sheets, and by the questionnaire filled out by each radiologist, were used as an important corollary to the quantitative data in arriving at selected performance criteria for future Remote Medical Diagnosis Systems. The importance of a qualitative assessment of the documented radiographic evaluation process cannot be underestimated, since the diagnosing radiologist at the diagnostic center terminal will be the end user of the RMDS. Therefore, the radiologists' reactions to RMDS functional capabilities and performance were of prime consequence. Analysis of the qualitative data addressed areas such as the following:

- a) Determine quality of received images by visual examination of photographs, by transmission mode.
 - Full scale images
 - Zoom images
- b) Summarize confidence and Overall Clinical Reading scores using mean and standard deviation, by transmission mode.
- c) Evaluate use of zoom controls by mode, testing sequence, radiologist, and Overall Clinical Reading.
- d) Establish mean, maximum, and minimum times required to diagnose one set of six radiographs, by transmission mode.
- e) Characterize test radiographs by DRF, zone, and pathology.
- f) Analyze radiologists' comments on test data sheets.
- g) Analyze radiologists' comments on questionnaire.

3.3 FINDINGS

At the conclusion of the data analyses, a comprehensive test report was prepared which organized and summarized the quantitative and qualitative analyses and results in the form of narrative, tables, and figures (ref 3). That report also includes a section on recommended functional and performance parameters for digitization, resolution, and SNR, to be input to an RMDS procurement specification. The

^{3.} NOSC TR 683, Remote Medical Diagnosis System (RMDS) Advanced Development Model (ADM) Radiology Performance Test Results, WT Rasmussen, PD Hayes, I Stevens (NOSC), FH Gerber (NRMC San Diego), JA Kuhlman and FW Hutzelman (WESTEC Services, Inc.), in process for publication.

quantitative and qualitative findings and interpretations within that report address the following:

- a) Indicate acceptance or rejection of the hypotheses (section 2.2).
- Provide quantitative measures of the effects of each experimental variable on diagnostic performance, independent of the other variables. For example, does the SNR, by itself, have a statistically significant influence on diagnostic performance? Which variable(s), if any, has (have) the most profound effect on diagnostic performance? Quantize the level of influence exerted by the variable(s).
- c) Determine statistically significant differences in diagnostic performance between each of the various transmission modes and the standard method.
- d) Point out any pathologies (of those provided) which do not lend themselves to confident and accurate diagnoses from transmitted radiographs.
- e) Provide guidelines to the performance parameters of digitization, resolution, and SNR for an RMDS procurement specification.

SECTION 4

RESOURCES

4.1 MATERIAL RESOURCES

The following resources were required:

- a) Six sets of six radiographs each (a total of 36), including templates for setting camera field of view for each radiograph.
- b) Two ADM RMDS terminals (one each, transmit and receive). The two RMDS terminals were wired back-to-back so that they could readily be switched between analog and digital transmission modes. The link included the circuitry for adding noise to the analog transmission line. In addition, the transmitting RMDS unit was equipped with monitoring instrumentation for specific and precise setting of the TV camera aperture (brightness), transmit black level, and video level.
- c) TV monitor (17-inch) on desk or table.
- d) Voice link between monitor location and the transmit RMDS room.
- e) Cassette tape recorder and tapes for recording test proceedings.
- f) Four-channel strip chart recorder to monitor subjects' trightness and contrast adjustments on TV monitor, and to record transmit black level and video level settings.
- g) Direct link from RMDS TV camera to TV monitor (for CCTV mode) via appropriate bandpass filter.
- h) Radiograph light box.
- i) Subjects' Test Data Sheets, with typewritten case history included.
- j) Observers' data collection sheets (for both RMDS and Control Tests).
- k) Experimental scenario, instructions, and instrumentation operation instructions.

4.2 PERSONNEL RESOURCES

Each test session involved one radiologist and two RMDS transmission equipment operators. Additionally, a technician familiar with the RMDS equipment was available to resolve any equipment problems.

4.3 SCHEDULE

4.3.1 RMDS Radiology Tests

The radiologists participating in the tests were scheduled at random, one per each 3- to 4-hour afternoon session, according to the radiologists' availability. The length of each session depended on how fast the radiologist could diagnose the radiographs. Each session included two or three trials. A test session did not end unless a trial had been completed. Each trial corresponded to a particular transmission mode and included six radiographs presented to the radiologist. Thus, each radiologist completed the test in two to three sessions.

4.3.2 Control Radiology Tests

Radiologists were scheduled in the same way as in 4.3.1, and test sessions were about as long. There was a total of nine trials per radiologist, and each session consisted of four to five trials. Thus, each radiologist completed the test in two sessions.

APPENDIX A

RADIOLOGISTS' INTRODUCTION TO RADIOLOGY TESTING

Prior to the first test session, each radiologist was briefed on the purpose of the RMDS; the reasons for and the objectives of the test; the capabilities, features, and limitations of the hardware; the test materials; and the test procedures. The following introductory material was given to and discussed with each radiologist.

INTRODUCTION TO RADIOLOGY TESTING

This is a Remote Medical Diagnosis System (RMDS), whose general mission is to improve medical diagnosis at remote sites (ship or shore) by exchanging medical data and diagnostic information between these remote sites and full-capability medical centers. The RMDS will enable the medical personnel at a remote site to contact a physician at a diagnostic center, either ashore or shipboard, and transmit the medical data needed for diagnosis such as patient history, laboratory tests, ECG tracings, x-ray images, images of a patient injury, heart-lung sounds, and verbal descriptions. By return link, the physician will be able to send diagnosis and treatment information. The communication requirements for this are satisfied by any two-way voice-grade narrowband communication channel such as telephone line, hf or uhf radio, or satellite links.

You are going to participate in a test to help determine video requirements for the transmission of x-ray images. This unit will be used as the receive unit, and the transmit unit is in the room next door. However, both units are identical and can be used for either transmitting or receiving.

We are now going to give you three example cases to demonstrate and familiarize you with the system. The first case I will run through quickly, but the second and third cases will be handled entirely by you and I will assist or answer any questions you may have.

- 1. You will be provided a documentation sheet, such as these, for each case in your test session. Some general history, symptomatic, or clinical data may be given. You are asked to record your findings and diagnoses, and indicate a level of confidence: 1=low to 5=high.
- 2. You will see the image of the x-ray on the monitor on the table. (For Control Group: You will also be asked to view x-ray films using the light box on the wall.)*
- 3. You may adjust the contrast and brightness of the monitor to suit yourself. These settings are being recorded. In addition, members of the Test Group will have the option of viewing the images in either positive or negative polarity.
- 4. If you want a close-up of any portion of the image, just tell the operator in the other room via the audio link you have. Use the plastic overlay on the monitor, and advise the operator which of the nine areas or portions thereof you would like enlarged. (For Test Group: If you request a close-up image, you may retain the full-size image on this second monitor by pushing this FRAME FREEZE button.)*

^{*}These statements were included in the introduction to the Control Group and Test Group, respectively, but subjects were not advised as to which group they belonged to.

- 5. The midio link between the two rooms will allow you to have two-way voice conversation with the operator if you have any problems or questions. However, the operator will not provide you with any additional data on the test cases. Also, you will be tape-recorded for documentation purposes during the test sessions.
- 6. Please don't push or adjust any other knobs on the monitor or the RMDS unit. Everything has been previously set for each test session.
- 7. After the three example cases, test cases will be shown to you in a set of six. These will be shown to you in a fixed order, and you will have a corresponding set of documentation sheets.
- 8. You will not be led astray on these cases. This is a test of the system, not a test of your abilities. If you have any additional comments, please write them down.

AFTER THE EXAMPLE CASES:

- 9. The next session of six cases may take approximately one-half hour to two hours to complete. This is due to the time required for the operator to set up and document the transmission at specific settings for consistency among all testing sessions. After the first session there will be a break and then a second session.
- 10. Please do not discuss your testing session, x-ray cases, or opinions of the system with any of your colleagues until after all testing has been completed.

APPENDIX B

TEST AND CONTROL SEQUENCE FOR RMDS RADIOGRAPHIC ANALYSIS

The following is a sequence of steps used during the testing to ensure that the image of an x-ray was repeated as identically as possible for each test subject.

TEST AND CONTROL SEQUENCE

Prior to any testing, radiographs were individually reviewed. The RMDS terminal adjustments were recorded for each radiograph. This allowed each radiograph to be presented identically to each subject. When the RMDS adjustments were recorded for each radiograph, a major consideration of the NOSC personnel was that the image presented be as near to the original radiograph as possible; ie, there was no attempt made to enhance any portion of the images. The following is the basic sequence used for both Test and Control Groups:

- 1. Before the radiologist arrived for testing, the RMDS was turned on and tested to ensure proper working order.
- 2. On the radiologist's first test period, a brief background was presented to familiarize the radiologist with the RMDS. During all test periods, the tape recorder in the Doctor's room was turned on and the door to the room was closed to prevent interference and distraction. Once the radiologist was isolated, the only communication was through a push-to-talk hand set.
- 3. In an adjacent room, an RMDS operator set up a radiograph according to the previously determined adjustments of brightness, contrast, and x-ray size. When the image was correct in reference to the prerecorded adjustments, a picture of the image was taken for reference by a monitor camera.
- 4. For Test Group subjects, the image was transmitted (in the appropriate mode) to the receive RMDS terminal. However, the image was withheld from display on the receive monitor during the transmission time to prevent the radiologist from seeing the slow-scan image development. When the radiologists indicated they were ready for another case, the full image was switched to their monitor. The only adjustments available to the radiologists were the contrast and brightness controls on their monitor.
- 5. When the radiologist signaled completion of diagnosis, the image on the remote monitor was switched off and recordings were made of any radiologist adjustments to the contrast and brightness of the remote monitor.

There were two variations to the basic sequence above: one was the zoom sequence and the second was the Control I sequence. The zoom sequence repeated steps 3 through 5 with the exception that in step 3 the adjustments of size, brightness and contrast were not prerecorded. This allowed for some enhancement when requested by the radiologist. The Control I sequence used the light box, during which the radiologists were given the radiographs one at a time until the diagnoses were completed.

APPENDIX C

RADIOLOGISTS' QUESTIONNAIRE FOLLOWING RADIOLOGY TESTING

After the completion of all tests, each radiologist was asked to complete the following questionnaire.

TEST GROUP* RADIOLOGY QUESTIONNAIRE

You have been involved in a test of the Remote Medical transmission (RMDS) to determine its effectiveness in transmitting x-ray images. Different transmitting modes and resolution levels have been used, which accounts for the differences in image quality between the various sets of cases. Much of the time required between transmission of each image has been due to the data collection procedure for these tests, and should not bias your opinion of the system's usefulness. Keep in mind that the system is intended to provide an emergency diagnostic consultation capability between medical personnel at remote or isolated sites and larger medical facilities.

We would like you to take a few more minutes to answer the following questions:

1. Do you feel that satisfactory radiology consultations for emergency cases can be made via the RMDS? (Please discuss.)

2. Do you feel that there are particular types of pathologies that may or may not be readily diagnosed using the RMDS? (Please indicate such types.)

3. Was the "zoom" capability (enlargement of a portion of the image) useful to you in making a diagnosis?

^{*}These questions were presented to members of the Test Group. However, the subjects were not advised as to which group they belonged to.

4.	If you used the "zoom" feature, did you save the full-sized image using the "video storage"? If so, was that useful and how?
5.	Would one image be sufficient for this type of system, or are two simultaneous images required? (Please discuss.)
6.	Did you use the "reverse polarity" feature (positive or negative image)? Would such a feature be of any use to you as a radiologist?
7.	Do you see a need for archiving some images on disc memory for later consultation?
8.	Please make any additional comments you wish.

CONTROL GROUP* RADIOLOGY QUESTIONNAIRE

You have been involved in a test of the Remote Medical Diagnosis System (RMDS) to determine its effectiveness in transmitting x-ray images. Different transmitting modes and resolution levels have been used, which accounts for the differences in image quality between the various sets of cases. Much of the time required between transmission of each image has been due to the data collection procedure for these tests, and should not bias your opinion of the system's usefulness. Keep in mind that the system is intended to provide an emergency diagnostic consultation capability between medical personnel at remote or isolated sites and larger medical facilities.

We would like you to take a few more minutes to answer the following questions:

1. Do you feel that satisfactory radiology consultations for emergency cases can be made via the RMDS? (Please discuss.)

2. Do you feel that there are particular types of pathologies that may or may not be readily diagnosed using the RMDS? (Please indicate such types.)

3. Was the "zoom" capability (enlargement of a portion of the image) useful to you in making a diagnosis?

^{*}These questions were presented to members of the Control Group. However, the subjects were not advised as to which group they belonged to.

4. Would one image be sufficient for this type of system, or are two simultaneous images required? (Please discuss.)

5. Do you see a need for archiving some images on disc memory for later consultation?

6. Please make any additional comments you wish.